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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,199	08/09/2005	Jean-Paul Gilbert Ricol	80350-1350	5197

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

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05/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,199	RICOL ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-19* is/are pending in the application.

4a) Of the above claim(s) *6-12,18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refer to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on February 24, 2009 is acknowledged. The traversal is on the ground(s) that applicant believes there is a common special technical feature at least linking groups I and group II. This is not found persuasive because although the restriction requirement did not detail the different technical features of group I and group II, the latter contains embodiments not required by the former. In addition, the inventions lack unity because the feature that is common to both groups does not make a contribution over the prior art (a textile support with lyophilized biocompatible material composed of hyaluronic acid, alginates, polypeptide or polcaprolactone) as demonstrated by the rejections below. Finally, should the invention of group I become allowable, the embodiments of group II that include the same technical feature as group I would be eligible for rejoinder.

Claims 6-12 and 18-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Orgill et al. (WO 00/16822 – see IDS) as evidenced by Summary of Safety and Effectiveness for PROLENE Soft (2000 Section 7 pages 25-27).

Orgill et al. disclose a PROLENE polypropylene mesh that is coated with a freeze dried (lyophilized) collagen (polypeptide) coating (see page 16 lines 5-16). The Summary of Safety and Effectiveness for PROLENE Soft discloses that PROLENE mesh is composed of a monofilament polypropylene mesh (see page 26 paragraph 4). Therefore claim 1 is unpatentable over Orgill et al. as evidenced by the Summary of Safety and Effectiveness for PROLENE Soft.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4 rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. in view of the Summary of Safety and Effectiveness for PROLENE Soft .

Orgill et al. teach a polypropylene mesh with a freeze dried collagen-glycosaminoglycan blend (see page 16 lines 5-16). In addition, Orgill et al. teach hyaluronic acid as an envisioned glycosaminoglycan (see page 7 line31-page 8 line 3;

instant claim 1). Orgill et al. go on to teach the polypropylene mesh Prolene™ as a particular envisioned mesh, but do not explicitly teach details about its structure.

The Summary of Safety and Effectiveness for PROLENE Soft teach that Prolene™ polypropylene meshes are knit monofilament (single thread) mesh structures see page 25 Device Description; instant claim 4). Since this was a known variety of Prolene™, it would have been obvious to one of ordinary skill in the art at the time of the invention to select this particular variety for the invention of Orgill et al. Therefore claims 1 and 4 are obvious over Orgill et al. in view of the Summary of Safety and Effectiveness for PROLENE Soft.

Claims 1-2 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. in view of the Summary of Safety and Effectiveness for PROLENE Soft as applied to claims 1 and 4 above, and further in view of Noishiki (US Patent No. 5,986,168).

Orgill et al. in view of the Summary of Safety and Effectiveness for PROLENE Soft make obvious a polypropylene mesh composed of single-strand threads with lyophilized hyaluronic acid on its surface (see claims 1 and 16). This modified reference does not explicitly teach the molecular weight of the hyaluronic acid.

Noishiki teach a prosthetic device with a bioabsorbable material (see abstract). In particular hyaluronic acid is taught as a known bioabsorbable material and its molecular weight is disclosed by Noishiki (see column 5 lines 66-67 and column 6 lines 19-20). This molecular weight is taught to range from 10,000 to 2,000,000 Daltons (see column

6 lines 21-22; instant claim 2). As a known option used in the same context, it would have been obvious to one of ordinary skill in the art at the time of the invention to select a hyaluronic acid between 10,000 to 2,000,000 Daltons for the invention of Orgill et al. in view of the Summary of Safety and Effectiveness for PROLENE Soft. Therefore claims 1-2 and 16 are obvious over Orgill et al. in view of the Summary of Safety and Effectiveness for PROLENE Soft and Noishiki.

Claims 1-2, 13-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. in view of the Summary of Safety and Effectiveness for PROLENE Soft as applied to claims 1 and 4 above, and further in view of Boone et al. (US Patent No. 6,294,170) and Wade et al. (US Patent No. 5,632,995).

Orgill et al. in view of the Summary of Safety and Effectiveness for PROLENE Soft make obvious a polypropylene mesh composed of single-strand threads with lyophilized hyaluronic acid on its surface (see claims 1 and 16). This modified reference does not explicitly teach the molecular weight of the hyaluronic acid.

Boone et al. teach hyaluronic acid used in a biological context (see column 28 lines 19-28). Further detail provided by Boone et al. regarding the hyaluronic acid teaches the molecular weight ranges known for use. In particular, weights between 1,000,000 and 2,000,000 Daltons are taught (see column 29 lines 12-17). Further, Wade et al. teach that hyaluronic acid of 1,200,000 Daltons in molecular weight was also known for use in a biological context (column 7 lines 13-18; instant claims 13-14). In light of the molecular weights of hyaluronic acid known for use in a biological context and the routine experimentation within the technical grasp of one of ordinary skill in the

art, it would have been obvious to one of ordinary skill in the art at the time of the invention use a molecular weight between 1,000,000 to 2,000,000 Daltons and in particular 1,200,000 Daltons, in the modified invention of Orgill et al. Therefore claims 1-2, 13-14, and 16 are obvious over Orgill et al. in view of the Summary of Safety and Effectiveness for PROLENE Soft, Boone et al, and Wade et al.

Claims 1, 3, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. in view of Kugel (US Patent No. 5,634,931).

Orgill et al. teach a polypropylene mesh with a freeze dried collagen-glycosaminoglycan blend (see page 16 lines 5-16). In addition, Orgill et al. teach hyaluronic acid as an envisioned glycosaminoglycan (see page 7 line31-page 8 line 3; instant claim 1). Orgill et al. go on to teach a polypropylene mesh as a particular envisioned mesh. The hyaluronic acid is taught by Orgill et al. to enhance the anti-adhesive properties of the coated structure (see page 8 lines 2-3). This reference does not explicitly teach the presence of a top layer of bi- or tri-dimensional structure in the mesh support.

Kugel teaches a hernia mesh patch preferable composed of a top and bottom layer of monofilament (single strand) polypropylene (see column 3 lines 61-64 and column 4 lines 37-46; instant claims 3 and 17). Each layer has both two (length and width) and three (length width and thickness/depth) dimensions. Since the inhibition of non-specific tissue adhesion between the hernia patch and surrounding organs/tissues is desirable, it would have been obvious to one of ordinary skill in the art at the time of

the invention to utilize the mesh structure of Kugel in the invention Orgill et al. Therefore claims 1, 3, and 17 are obvious over Orgill et al. in view of Kugel.

Claims 1-2, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. in view of Noishiki and Kugel.

Orgill et al. teach a polypropylene mesh with a freeze dried collagen-glycosaminoglycan blend (see page 16 lines 5-16). In addition, Orgill et al. teach hyaluronic acid as an envisioned glycosaminoglycan (see page 7 line31-page 8 line 3; instant claim 1). Orgill et al. go on to teach a polypropylene mesh as a particular envisioned mesh. The hyaluronic acid is taught to by Orgill et al. enhance the anti-adhesive properties of the coated structure (see page 8 lines 2-3). This reference does not explicitly teach the presence of a top layer of bi- or tri-dimensional structure in the mesh support or the molecular weight of the hyaluronic acid.

Kugel teaches a hernia mesh patch preferable composed of a top and bottom layer of monofilament (single strand) polypropylene (see column 3 lines 61-64 and column 4 lines 37-46; instant claims 3 and 17). Each layer has both two (length and width) and three (length width and thickness/depth) dimensions.

Noishiki teach a prosthetic device with a bioabsorbable material (see abstract). In particular hyaluronic acid is taught as a known bioabsorbable material and its molecular weight is disclosed by Noishiki (see column 5 lines 66-67 and column 6 lines 19-20). This molecular weight is taught to range from 10,000 to 2,000,000 Daltons (see column 6 lines 21-22; instant claim 2).

Since the inhibition of non-specific tissue adhesion between the hernia patch and surrounding organs/tissues is desirable, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the mesh structure of Kugel in the invention Orgill et al. As a known option used in the same context, it would have been obvious to one of ordinary skill in the art at the time of the invention to select a hyaluronic acid between 10,000 to 2,000,000 Daltons for the invention of Orgill et al. Therefore claims 1-2 and 15 are obvious over Orgill et al. in view Kugel and Noishiki.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635